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WHO's Pandemic Influenza Preparedness Framework: A Milestone in Global Governance for Health

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After years of negotiations, the World Health Organization (WHO) reached agreement on a pandemic influenza preparedness (PIP) framework for the sharing of influenza viruses and access to vaccines and other benefits in April 2011.[1] The framework addresses a troubling controversy—should low- and middle-income countries share influenza virus specimens with WHO without assurances that benefits derived from sharing will be equitably distributed?

During the avian influenza A(H5N1) outbreaks in late 2006, Indonesia refused to share virus specimens with WHO, claiming it was unfair to give pharmaceutical companies access. Industry would use viruses to patent vaccines and antiviral medications that Indonesia could not afford. Indonesia asserted sovereignty over viruses isolated within its territory, grounded on the Convention on Biological Diversity. Indonesia also argued that the 2005 International Health Regulations did not require states to share H5N1 viruses.[2] The international community feared that Indonesia's refusal to share would impede surveillance and response, particularly because Asia was the epicenter of the global H5N1 outbreak.[3] Serious health and political repercussions could result if states failed to cooperate when confronting a common threat.

In May 2007, WHO member states commenced negotiations on virus and benefit sharing to strengthen influenza surveillance and response.[4] Negotiations in intergovernmental meetings[5] and an open-ended working group[6] proved difficult—the problems were complex and states had divergent interests, particularly on intellectual property rights.[7] The 2009 influenza A(H1N1) pandemic deepened developing-country mistrust because vaccines were not equitably shared.[8] In October 2010, Convention on Biological Diversity parties reasserted state sovereignty over biological materials within their territories.[9] Finally, after nearly 4 years of arduous negotiations, WHO's director-general announced the WHO pandemic framework on April 16, and the World Health Assembly approved it in May.[10]

PIP Framework

Objective and Principles. The framework governs sharing "H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits," but does not apply to seasonal influenza or noninfluenza biological materials. It improves preparedness through WHO's Global Influenza Surveillance and Response System (GISRS) by encouraging states to share viruses and enhance equitable access to benefits. Framework principles include sovereignty over biological resources, virus and benefit sharing on an equal footing, and financing mechanisms for equitable access to benefits.

Legal Status. The framework is not legally binding. WHO did not exercise its constitutional authority to adopt international law, and it contains permissive language—eg, member states "should" share viruses and benefits. The framework uses standard agreements for laboratories and manufacturers participating in GISRS, creating legal consequences for contracting parties.

Virus-Sharing System. The framework facilitates sharing viruses and genetic sequence data and creates a traceability mechanism, supported by 2 standard material transfer agreements. The framework encourages member states to share "PIP biological materials"—specimens containing H5N1 or other influenza viruses with human pandemic potential—with a WHO Collaborating Centre on Influenza or WHO H5 Reference Laboratory. When member states provide PIP biological materials, they consent to transfer and use of these materials within and outside GISRS, subject to the applicable standard material transfer agreement. Member states may share PIP biological materials with other entities provided that they give the same materials to a GISRS facility. Genetic sequence data "should be shared . . . with the originating laboratory and among WHO GISRS laboratories." The framework directs WHO's director-general to strengthen genetic sequence data sharing by addressing access, transparency, and political sensitivity concerns. WHO

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must establish an influenza virus tracking mechanism to monitor movement of PIP biological materials into, within, and out of GISRS. The influenza virus tracking mechanism creates transparency to ensure that virus transfer and use conform to framework principles.

The standard material transfer agreements govern PIP biological materials transfers within and outside GISRS. The first standard material transfer agreement covers transfers between GISRS laboratories recognized or designated by WHO, requiring them to comply with terms of reference and with WHO and national biosafety standards. This first agreement encourages laboratories not to seek intellectual property rights on PIP biological materials. The second agreement applies to transfers from WHO to entities outside GISRS, such as vaccine manufacturers.

Benefit-Sharing System. The benefit-sharing system contains many components, but the most significant ones require industry to pay half of GISRS's annual operating costs and provide benefits under the second standard material transfer agreement (eg, vaccine donations). These contributions give industry access to PIP biological materials in exchange for assisting developing countries. Although requiring manufacturers to provide equity-enhancing benefits, the framework does not direct developed member states to provide specific benefits for developing countries (eg, vaccine donations).

Governance and Review. The World Health Assembly, the WHO director-general, and an advisory group established during the negotiations will oversee the framework's implementation. The independent advisory group "will provide evidence-based reporting, assessment and recommendations." WHO will review the framework in 2016, and the World Health Assembly will consider revisions in 2017.

Value of the PIP Framework

The framework seeks to strengthen pandemic influenza surveillance and response while enhancing global equity. Although the framework emphasizes the norm of sharing viruses, it does not create legally binding obligations on virus sharing. During the H5N1 and H1N1 crises, all states shared viruses, except for Indonesia's H5N1 refusals. The framework reinforces a global norm but does not alter the status quo. Genetic sequence data sharing also does not represent a major shift, evidenced by the WHO director-general's obligation to address obstacles to sharing these data. The framework's most progressive reform for surveillance and response is increased transparency of virus transfers through the influenza virus tracking mechanism and standard material transfer agreements, which bolsters GISRS legitimacy.

The framework's greatest accomplishment for equity is to require industry contributions to GISRS' operating costs and through benefits provided under the second standard material transfer agreement. Private-sector contributions will benefit developing countries by increasing access to technologies and capacity-building resources. However, private-sector acquiescence reflects the framework's avoidance of intellectual property right disputes that complicated the negotiations. The framework's most glaring omission is the absence of even "soft" norms encouraging developed countries to make specific equity-enhancing contributions to developing countries, such as donating portions of purchased vaccine.

The framework is a landmark in global governance for health, representing the first international agreement on influenza virus and benefit sharing. The framework, however, reflects compromises that could jeopardize more equitable allocation of benefits in a future pandemic. Implementing innovative global governance strategies is often frustrating, underfunded, and inadequate.

The framework emerges as political and financial capital for global health is decreasing. When the next pandemic occurs, will the international community identify the threat and deploy effective therapeutic technologies? Will scientific research and innovations be shared more equitably? Global cooperation and fair allocation of life-saving resources are essential for an effective and humane response to global health threats.

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